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| 10/700,003      | 11/03/2003  | Qiong Cheng          | CL1646USDIV         | 5012             |

23906 7590 08/10/2005

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WILMINGTON, DE 19805

EXAMINER

PAK, YONG D

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
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1652

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/700,003

Applicant(s)

CHENG ET AL.

Examiner

Yong D. Pak

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address.--

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 May 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 23-29 and 36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23-26, 28, 29 and 36 is/are allowed.
- 6) ☒ Claim(s) 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5/24/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This application is a divisional of 09/934,903, now issued as U.S. Patent No. 6,660,507.

The amendment filed on May 24, 2005, amending claims 23, 25 and 27, has been entered.

Claims 23-29 and 36 are pending and are under consideration.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on May 24, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Terminal Disclaimer***

The terminal disclaimer filed on May 24, 2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 09/941,947 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### ***Response to Arguments***

Applicant's amendment and arguments filed on May 24, 2005, have been fully considered and are deemed to be persuasive to overcome the rejections previously

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applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 27 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Claim 27 is drawn to a method of producing isoprenoid compounds by transforming the plant cells recited in claim 27. The scope of the claim is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of plant host cells, broadly encompassed by the claims.

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However, in this case the disclosure is limited to a method for transforming bacterial host cells with a polynucleotide encoding a pyrophosphate dependent phosphofructokinase. In order to produce carotenoid compounds, plant host cells must integrate the foreign polynucleotide and express a functional, active enzyme. However, successful expression and stability of foreign polynucleotides introduced into plant host cells remain unpredictable (Newell et al., pages 60-61). Therefore, it would require undue experimentation of the skilled artisan to transform all the plant cells recited in the claim and use them to produce carotenoid compounds. In view of the great breadth of the claim, amount of experimentation required to transform all the recited plant cells, the lack of guidance, working examples, and unpredictability of the art in successfully transforming the recited plant cells and expressing a functional enzyme, the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to make the full scope of transforming the plant cells encompassed by the claim.

The specification does not support the broad scope of the claims which encompass a method for producing isoprenoid compounds by transforming all the recited plant cells with a polynucleotide, because the specification does not establish: (A) a method of successfully transforming the recited plant cells with a polynucleotide encoding a pyrophosphate dependent phosphofructokinase and SEQ ID NO:4 and expressing functional enzymes; (B) a rational and predictable scheme for transforming all the recited plant cells with a polynucleotide encoding a pyrophosphate dependent

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phosphofructokinase; and (C) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including a method for obtaining isoprenoid compounds using all the recited plant cells transformed with a polynucleotide encoding a pyrophosphate dependent phosphofructokinase. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of the recited plant cells expressing a functional enzyme encoded by a polynucleotide encoding a pyrophosphate dependent phosphofructokinase and SEQ ID NO:4 recited in the claim are unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

In response to the previous Office Action, applicants have traversed the above rejection.

Applicants argue that claim 27 meets the enablement requirement because the specification gives a detailed description of methods and materials needed for the transformation of a wide variety of plant species and that a person of skill in the art, given said teaching, would be able to make and use the invention. Examiner respectfully disagrees. The specification provides a general teaching and guidance in transforming plant cells with foreign polynucleotides. However, it would require undue

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experimentation of the skilled artisan to transform all the plant cells recited in the claim wherein the foreign polynucleotide (SEQ ID NO:3) is stably integrated into the host and the transformed host expresses a functional enzyme, which is required to produce carotenoid compounds. In view of the great breadth of the claim, amount of experimentation required to transform all the recited plant cells, the lack of guidance, working examples, and unpredictability of the art in successfully transforming the recited plant cells and expressing a functional enzyme, the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to make the full scope of stably transforming the plant cells encompassed by the claim.

Applicants request that the Examiner specifically point out what aspect of the specification is deficient in teaching the skilled person how to use the present genes in plants to make the claimed product. Although transformation of some plant cells with foreign polynucleotides is known, stability of foreign polynucleotides introduced into plant host cells and expression of a functional enzyme remains unpredictable and requires undue experimentation (Newell et al. pages 60-61). Plant cells expressing a functional enzyme are necessary in order to practice the claimed invention. Further, the specification only teaches a general procedure for transformation of plant cells. It is silent on specific guidance required to transform any or all the diverse set of host cells recited in the claims. It is this specific guidance that applicants do not provide. Without specific guidance, those skilled in the art will be subjected to undue experimentation of transforming the recited plant cells expressing a functional enzyme. Further, the

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specification does not teach a universal method that can be used to transform any or all plant host cells and therefore, one skilled in the art will be subjected to undue experimentation to transform the recited plant cells. Hence the rejection is maintained.

***Allowable Subject Matter***

Claims 23-26, 28-29 and 36 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935.



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The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Yong D. Pak  
Patent Examiner 1652



Manjunath Rao  
Primary Patent Examiner 1652